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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,094	10/22/2004	Abdurrahman Mithat Bozdayi	BJS-2551-158	4496

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EXAMINER	
KINSEY WHITE, NICOLE	
ART UNIT	**PAPER NUMBER**
1648	
MAIL DATE	**DELIVERY MODE**
12/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,094	BOZDAYI, ABDURRAHMAN MITHAT	
	Examiner	Art Unit	
	Nicole Kinsey White, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 37-39* is/are pending in the application.

4a) Of the above claim(s) *31-35 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6,8-30,38 and 39* is/are rejected.

7)☐ Claim(s) *3 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/27/2007 and 9/17/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 12, 15, 19, 22, 26 and 30 are objected to because of the following informalities:

Claim 12 should recite "a variant" instead of "an variant."

Claim 15 should recite "claim 13" instead of "claims 13."

In claims 15 and 19, the phrase "discriminatory signals relating to codon 204 and to codon 180 obtained in (ii) of said" in part (iii) should be deleted for clarity.

Claims 22 and 26 are missing "and" between part (i) and part (ii).

Claim 30 should recite "said oligonucleotide is" instead of "said oligonucleotide are."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-20, 25-30, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining resistance to HBV nucleoside analog reverse transcriptase inhibitors (lamivudine) by determining the presence of mutations at codon 180 and/or codon 204 of the reverse transcriptase domain, does not reasonably provide enablement for determining resistance to all HBV

antiviral drugs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a method (and a kit) for detecting resistance to any HBV antiviral drug by detecting the presence of an HBV polynucleic acid or fragment thereof that has a methionine at codon 180 and/or serine at codon 204 of the HBV reverse transcriptase domain.

According to the specification, mutations at codon 180 and/or 204 relate to resistance of specific HBV nucleoside analog reverse transcriptase inhibitors such as lamivudine. However, there is no teaching in the specification that these mutations are related to resistance to all known HBV antiviral drugs (e.g., Intron A, Pegasys, and other nucleoside analogs such as Entecavir and Telbivudine).

Given the breadth of the claims and the lack of guidance in the specification, the full scope of the method and kit claims is not enabled.

Claims 13-16 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting the presence of HBV in a sample by detecting polynucleic acid comprising the reverse transcriptase domain with a mutation at codon 204, wherein codon 204 is a serine, does not reasonably provide enablement for detecting the presence of HBV in a sample by detecting an HBV polynucleic acid fragment comprising codon 204 of the reverse transcriptase domain, wherein codon 204 is a serine. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a method (and a kit) for detecting the presence of a HBV in a biological sample, by detecting the presence of an HBV polynucleic acid or fragment comprising codon 204 (serine) of the HBV reverse transcriptase domain.

The claims, as written, read on a trinucleotide that encodes serine (i.e., a fragment that comprises codon 204 (serine)) and read on other non-reverse transcriptase HBV proteins that contain a serine (i.e., an HBV polynucleic acid that contains serine 204 from HBV reverse transcriptase).

According to the specification, an isolated HBV reverse transcriptase domain nucleic acid or polypeptide can be used to detect a variant HBV in a sample by determining if codon 180 of the domain is a methionine and/or codon 204 of the domain is a serine. However, there is no teaching in the specification that a fragment of any size (e.g., a trinucleotide encoding serine) or a non-reverse transcriptase HBV protein that contains serine 204 from reverse transcriptase can be used to detect a variant HBV in a sample.

Given the breadth of the claims and the lack of guidance in the specification, the full scope of the method and kit claims is not enabled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, 8-12, rejected under 35 U.S.C. 102(b) as being anticipated by Petzold et al. (GenBank Accession No. AJ131956, Submitted 05-JAN-1999).

The claims are drawn to an isolated HBV polynucleic acid or a fragment thereof, said polynucleic acid or said fragment comprises codon 204 of the HBV reverse transcriptase domain, wherein said codon 204 encodes a serine. The HBV polynucleic acid or fragment can further comprise codon 180 of the HBV reverse transcriptase domain, wherein said codon 180 encodes a methionine.

Petzold et al. discloses an HBV polynucleic acid (and polypeptide) for the surface antigen, said nucleic acid (and polypeptide) contains codon 180 (methionine) and codon 204 (serine) from HBV reverse transcriptase.

Claims 3 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole Kinsey White, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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